

71

11. The method of claim 1, which provides a dosage amount of fentanyl when administered to humans which is substantially dose proportional to the dosage which contains about 400 mcg fentanyl selected from the group consisting of about 100 mcg, about 200 mcg, about 600 mcg, about 800 mcg, and provides one or more pharmacokinetic values selected from the group consisting of: mean  $AUC_{last}$ , mean  $AUC_{inf}$  and mean  $AUC_{extrap}$ .

12. The method of claim 1, which provides a substantially dose proportional mean  $AUC_{last}$  based on a mean  $AUC_{last}$  of about  $4.863 \pm 1.70821$  hr\*ng/mL for a 400 mcg fentanyl dose when administered to humans.

13. The method of claim 1, wherein the sublingual spray formulation comprises a 400 mcg dose of fentanyl, providing a geometric mean  $\ln(C_{max})$  of about 0.7865 ng/mL when a dose is administered to humans.

14. The method of claim 1, wherein the sublingual spray formulation comprises a 400 mcg dose of fentanyl, providing a mean  $F(AUC_{last})$  of about  $0.721 \pm 0.199$  ng/mL when a dose is administered to humans.

15. The method of claim 1, wherein the sublingual spray formulation comprises a 400 mcg dose of fentanyl when a dose is administered to humans, providing a mean  $F$  (bio-availability) selected from the group consisting of: about  $71\% \pm 16\%$ ,  $0.721 \pm 0.199$  based on  $AUC_{last}$  and about  $0.756 \pm 0.212$  based on  $AUC_{inf}$  or combinations thereof.

16. The method of claim 1, wherein the sublingual spray formulation further comprises water.

17. The method of claim 1 wherein the sublingual formulation provides a substantially dose proportional mean  $C_{max}$  based on a mean  $C_{max}$  of about  $0.813$  ng/mL  $\pm 0.252$  for a 400 mcg fentanyl dose when administered to humans.

72

18. The method of claim 1 wherein the sublingual formulation provides a substantially dose proportional mean  $AUC_{last}$  based on a mean  $AUC_{last}$  of about  $4.863 \pm 1.70821$  hr\*ng/mL for a 400 mcg fentanyl dose when administered to humans.

19. A method of manufacturing a sublingual spray formulation comprising an effective amount of fentanyl and at least one pharmaceutically acceptable excipient comprising:

admixing fentanyl, purified water and dehydrated alcohol and placing the mixture into a sublingual delivery device; the formulation providing a mean  $T_{max}$  of about  $1.28 \pm 0.60$  hours when a dose is administered sublingually to humans and upon delivery, providing a mean aerodynamic particle size of at least about 10 microns; wherein said sublingual spray formulation comprises: from about 0.1% to about 0.8% by weight of fentanyl or a pharmaceutically acceptable salt thereof; from about 50% to about 60% by weight of ethanol; and from about 4% to about 6% by weight of propylene glycol.

20. A method of treating pain comprising administering to a patient in need thereof a propellant-free sublingual spray formulation comprising an effective amount of fentanyl, the formulation providing a mean time to 60% maximum plasma concentration ( $T_{max}$ ) of fentanyl of about 10 minutes; and wherein said sublingual spray formulation comprises drop-lets having a mean diameter of at least about 10 microns; wherein said sublingual spray formulations comprises:

from about 0.1% to about 0.8% by weight of fentanyl or a pharmaceutically acceptable salt thereof; from about 50% to about 60% by weight of ethanol; and from about 4% to about 6% by weight of propylene glycol.

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